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EXAMINER	
MCCLAIN-COLEMAN, TYNESHA L.	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,151	LAHRSOW, JOBST	
	Examiner	Art Unit	
	TYNESHA MCCLAIN-COLEMAN	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060714*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 17 recites the limitation "said first calcium-complexing acid" in lines 3 and 4 of claim 17. There is insufficient antecedent basis for this limitation in the claim. Clarification could be achieved by amending "calcium-complexing acid" in line 2 of claim 17 to "first calcium-complexing acid."

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 11, 13-16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by *Muhler et al.* US 4400372 (hereinafter "*Muhler*").

6. With respect to claims 11 and 20, *Muhler* discloses a method of manufacturing chewing gum in which the source of acid is blended thoroughly into the gum base

mixture (Example I, column 7, lines 25-45). The finished gum is removed from the mixer, shaped into the desired form, dusted with mannitol or starch, and allowed to cool after which it may be wrapped and packaged (Example I, column 7, lines 45-51).

7. For the source of acid and calcium, mixtures of acids producing an aqueous pH in the appropriate range can be used in order to bring about the enhanced enamel polishing capability of the final gum product (column 16, lines 28-31). In one particular example, monobasic calcium phosphate ($Ca(H_2PO_4)_2$) (which is an alkaline earth metal salt of the forgoing acid, column 3, lines 50-52) is combined with phosphoric acid (H_3PO_4) (Table 9, column 16).

8. Regarding claims 13-16, *Muhler* discloses the acid source may be one or more organic acids, inorganic acids, or acid salts thereof (column 3, lines 38-40). Carboxylic acids (claim 14) such as citric acid (claim16), malic acid (claim 16), and lactic acid (claim 15) and mixtures thereof (claim 13) may be used (column 3, lines 43-46).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 11, 14-16, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Broderick et al.* WO 00/62762 (hereinafter "*Broderick*") in view of *Muhler et al.* US 4400372 (hereinafter "*Muhler*").

12. With respect to claims 11 and 20, *Broderick* discloses a gum composition comprising calcium carbonate, citric acid, and phosphoric acid (Example 3, pages 10-11). *Broderick* also discloses the calcium carbonate and the citric acid in a pre-blended mixture (page 11, lines 21-22).

13. However, *Broderick* does not disclose mixing the calcium and acid mixture into a thickener, shaping the mixture, and drying the mixture.

14. *Muhler* disclosees a method of manufacturing chewing gum in which the source of acid is blended thoroughly into the gum base mixture (Example I, column 7, lines 25-45). The finished gum is removed from the mixer, shaped into the desired form, dusted with mannitol or starch, and allowed to cool after which it may be wrapped and packaged (Example I, column 7, lines 45-51).

15. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare the gum taught by *Broderick* with the method disclosed by *Muhler*.

16. One having ordinary skill in the art would have been motivated to do this because the method disclosed by *Muhler* is a conventional chewing gum manufacturing technique used to prepare regular and sugarless chewing gums (*Muhler*, column 7, lines 25-27).

17. Regarding claims 14-16, *Broderick* discloses citric acid (claims 14 and 16) and phosphoric acid used in example 3 (pages 10-11). *Broderick* also discloses food grade acid is chosen from the group consisting of: lactic acid (claims 14 and 15), phosphoric acid, citric acid (claims 14 and 16), and malic acid (claims 14 and 16) may be used as well.

18. With respect to claim 19, *Broderick* discloses calcium carbonate used as the calcium source in example 3 (pages 10-11).

19. Claims 11, 12, 14-16, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Wiedemann* CA 2138780 (hereinafter "*Wiedemann*") in view of *Muhler et al.* US 4400372 (hereinafter "*Muhler*").

20. Regarding claims 11 and 20, *Wiedemann* discloses a preparation containing dissolved or easily dissolved soluble calcium and dissolved or easily soluble phosphate to be used in a chewable mass (page 2, 1st paragraph). One part of the phosphate is

provided as H_2PO_4 ion i.e. only simply dissociated in solution. The undissociated protons, fixed to the phosphate, must be additionally added. This can be done, e.g. in the form of citrate or another acid used in confectionary making for aromatizing. The use of calcium chloride as a calcium donor is also conceivable (page 4, 1st paragraph). Sugar substitutes and/or gelatine and/or gum arabic and/or chewable mass may be used as the base mass (page 3, 3rd paragraph).

21. It is well known in the art that the H_2PO_4 ion is the conjugate base of phosphoric acid (H_3PO_4) in the aqueous form.

22. However, *Wiedemann* does not disclose shaping the mass and drying the mass.

23. *Muhler* discloses a method of manufacturing chewing gum in which the source of acid is blended thoroughly into the gum base mixture (Example I, column 7, lines 25-45). The finished gum is removed from the mixer, shaped into the desired form, dusted with mannitol or starch, and allowed to cool after which it may be wrapped and packaged (Example I, column 7, lines 45-51).

24. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare the gum taught by *Wiedemann* with the method disclosed by *Muhler*.

25. One having ordinary skill in the art would have been motivated to do this because the method disclosed by *Muhler* is a conventional chewing gum manufacturing technique used to prepare regular and sugarless chewing gums (*Muhler*, column 7, lines 25-27).

26. With respect to claim 12, *Wiedemann* discloses sugar substitutes and/or gelatine and/or gum arabic and/or chewable mass may be used as the base mass (page 3, 3rd paragraph).

27. Regarding claims 14-16, *Wiedemann* discloses lactic acid (claims 14 and 15), malic acid (claims 14 and 16), and general fruit acid (claim 14) are examples of acids that may be used with the phosphate ion (page 4, 1st paragraph).

28. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Wiedemann* CA 2138780 (hereinafter "*Wiedemann*") in view of *Muhler et al.* US 4400372 (hereinafter "*Muhler*") as applied to claim 11 above, and further in view of *Yang et al.* US 2001/0051197 (hereinafter *"Yang"*).

29. With respect to claims 17 and 18, *Wiedemann* in view of *Muhler* discloses a method of producing a gum composition comprising combining aqueous phosphoric acid with acids such as lactic acid, malic acid, and general fruit acid, adding a dissolved or easily soluble calcium source such as calcium chloride, and using sugar substitutes and/or gelatine and/or gum arabic and/or chewable mass may be used as the base mass (*Wiedemann*, page 4, 1st paragraph and page 3, 3rd paragraph). The source of acid is slowly added to the gum base and thoroughly blended. The gum is then shaped into the desired form, dusted with mannitol or starch, and allowed to cool, after which it may be wrapped and packaged (*Muhler*, Example I, lines 25-51).

30. However, *Wiedemann* in view of *Muhler* does not disclose adding a first calcium-complexing acid (pyruvic acid).

31. *Yang* discloses adding organic acids, such as citric acid, malic acid, and pyruvic acid, to a calcium source (paragraph [0162]).

32. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to incorporate the acids disclosed by *Yang* into the method of making a gum composition disclosed by *Wiedemann* in view of *Muhler*.

33. One having ordinary skill in the art would have been motivated to do this because *Yang* teaches when at least two different organic acids are combined with a calcium salt, the water solubility of the calcium is enhanced (paragraph [0162]).

34. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Wiedemann* CA 2138780 (hereinafter "*Wiedemann*").

35. With respect to claim 21, *Wiedemann* discloses more or less 0.9 to 3.6 weight percent of calcium (compounds) present in chewable sweets (page 5, section a and page 6, lines 1st paragraph).

36. If 3g of the final product (chewable sweets) is present, the amount of calcium (compounds) present would be calculated to about 9.0 g/kg for 0.9% and 36 g/kg for 3.6%.

37. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to interpret the chewable sweet composition disclosed by *Wiedemann* to include about 9.0 g/kg.

38. One having ordinary skill in the art would have been motivated to do this because the references teaches more or less (about) 0.9%, which is interpreted to included

weight percentages slightly below 0.9%. Thus, the range disclosed by *Wiedemann* overlaps the range claimed by the applicant. Also, *Wiedemann* teaches an adequate amount of dissolved mineral (essentially calcium and phosphate) must be present in order to rinse the lesion and facilitate a complete and deep remineralization of the lesion.

39. Regarding claim 22, *Wiedmann* discloses 100 to 300 mMol of phosphate content per kg of chewable sweet mass is present (page 6, 2nd paragraph).

40. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Broderick et al.* WO 00/62762 (hereinafter "*Broderick*").

41. With respect to claims 21 and 23, *Broderick* discloses the chewing gum will comprise approximately 0.1% to about 20% by weight calcium carbonate (page 6, lines 10-11).

42. If 3g of the final product (chewing gum) is present, the amount of calcium carbonate present would be calculated to about 1 g/kg for 0.1% and 200g/kg for 20%.

43. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to interpret the chewing gum disclosed by *Broderick* to include about 1.4g/kg to 9.0 g/kg and 2.3 g/kg to 7g/kg of calcium content.

44. One having ordinary skill in the art would have been motivated to do this because the reference teaches approximately 0.1%, which is interpreted to include weight percentages slightly above 0.1%, such as 0.14% (1.4 g/kg) and .3% (3 g/kg). Thus, the range disclosed by *Broderick* encompasses the ranges claimed by the

applicant. Also *Broderick* teaches sufficient levels of calcium carbonate are needed in order to enhance the remineralization of the tooth enamel.

45. Regarding claim 22, *Broderick* discloses 1.00% of phosphoric acid present in 3g of cinnamon chewing gum (Example 3, pages 10-11). The phosphoric acid content is calculated to be 10g/kg which falls within the applicant's claimed range of 15 and 500 mMol/kg (which is 1.4 g/kg to 48 g/kg as disclosed on page 8, lines 5-6 of the specification).

Conclusion

46. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TYNESHA MCCLAIN-COLEMAN whose telephone number is (571)270-1153. The examiner can normally be reached on Monday - Thursday 7:30AM - 5:00PM Eastern Time.

47. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on (571)272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

48. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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